

REMARKS

Claims 1-24 are cancelled herein without prejudice or disclaimer, and claims 25-53 are new. The new claims find basis in claims 1-24 as originally filed, and representative basis for the claims is in paragraphs 0008, 0009, 0010, 0017, 0019, 0041, 0051, 0070, 0078, 0079, 0080, 0081, 0089, 0092, 0098 and 0132 of the specification, for example. Accordingly, no prohibitive new matter is introduced by entry of new claims 25-53.

The Office's objection to claim 13 is moot as new claims 25-53 do not repeat the term "all operably linked." Similarly, the rejection of claims 6-12 under 35 USC 112, second paragraph, for alleged indefiniteness is inapplicable to the new claims because the term "administering an expression vector, wherein said expression vector is expressed in dendritic cells" is not present in the new claims.

The Office's rejections of (i) claims 6-8, 13, 21, 23 and 24 under 35 USC 102(a) in view of Dicker, (ii) claims 1-4, 6-9, 11, 13-18 and 20-23 under 35 USC 103(a) in view of Dicker and Nair, and (iii) claim 19 under 35 USC 103(a) in view of Dicker, Nair and Shu, also are inapplicable to the new claims. Subject matter of original claim 5, present in independent claims 25 and 44, is directed in part to a non-protein ligand and was not subject to these rejections.

The Office's rejection of claims 1-24 under 35 USC 112, first paragraph, for alleged lack of enablement, also is inapplicable to the new claims as the specification provides full support of the claim scope. In particular, the specification provides multiple working examples in support of the claimed subject matter, an *Ex Parte Foreman* factor bearing on enablement addressed in *In re Wands*. For example,

- (i) nucleic acids of the claims are described in paragraphs 0217 to 0218;
- (ii) *ex vivo* activation of antigen presenting cells is set forth in paragraphs 0225 to 0227, paragraphs 0228 to 0230 and paragraph 0233;
- (iii) eliciting an immune response by *ex vivo* transduction of antigen presenting cells is demonstrated in paragraphs 0231 to 0232; and

(iv) eliciting an immune response by *in vivo* transduction of antigen presenting cells is set forth in paragraphs 0236 to 0238 and in paragraphs 0243 to 0244.

In addition to this extensive set of working examples, the specification also provides clear guidance to the person of ordinary skill in the art for the scope of the claimed subject matter, another factor addressed in *In re Wands*. For example, the specification provides clear guidance for multiple membrane targeting regions in paragraph 0096, multiple ligands and ligand-binding regions in paragraphs 0082 to 0095 and CD40 cytoplasmic regions in paragraphs 0078 to 0080.

Given that working examples in the specification demonstrated an inducible CD40 chimeric protein activated antigen presenting cells and induced immune responses, the person of ordinary skill in the art could readily modify portions of the chimeric protein as a matter of routine experimentation in view of the specific guidance from the specification. The Court of Appeals for the Federal Circuit has found some experimentation may be necessary to produce an invention, and routine experimentation does not preclude a finding of enablement (*Monsanto Co. v. Scruggs*, 459 F.3d 1328; 79 USPQ.2d 1813 (Fed. Cir. 2006) and *In re Wands* (supra)). These factors coupled with the high level of skill in the art for technology pertaining to the subject matter of claims 25-32 leads to the conclusion that any experimentation associated with the full claim scope is routine and not undue. Accordingly, the new claims are fully enabled by the specification and the rejection of claims 1-24 is inapplicable.

CONCLUSIONS

Applicants respectfully assert that claims 25-53 are in condition for allowance. The Examiner is requested to call the undersigned representative for any reason that would advance prosecution of the instant patent application.

In the unlikely event a fee calculation document or other pertinent document is separated from this submission and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-3473**.

Respectfully submitted,

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